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Indian Standard SPECIFICATION FOR SPRAY, MACINTOSH'S PATTERN (First Revision)

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INDIAN STANDARDS INSTITUTION
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NEW DELHI 110002

Indian Standarð

SPECIFICATION FOR SPRAY, MACINTOSH'S PATTERN

(First Revision)

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(Continued on page 2)

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Indian Standard

SPECIFICATION FOR SPRAY, MACINTOSH'S PATTERN

(First Revision)

0. FOREWORD

- **0.1** This Indian Standard (First Revision) was adopted by the Indian Standards Institution on 27 December 1985, after the draft finalized by the Anaesthetic Resuscitation and Allied Equipment Sectional Committee had been approved by the Consumer Products and Medical Instruments Division Council.
- **0.2** The need for this standard has been felt because it is one of the most widely used items by anaesthetists in hospitals. Macintosh's pattern spray is mostly used in topical analgesia.
- **0.3** This standard is one of a series of Indian Standards dealing with anaesthetic equipment and medical breathing machines.
- **0.4** This standard was first published in 1975. The first revision of this standard has been undertaken to incorporate requirements like tolerances on various dimensions, correct reference to the material and performance test such as autoclaving test. A suitable sampling plan is also included in this revision.
- **0.5** For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS: 2-1960*. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

1. SCOPE

1.1 Specifies dimensional and other requirements for Macintosh's pattern spray for use in topical analgesia.

^{*}Rules for rounding off numerical values (revised).

2. MATERIAL

- 2.1 Metal Parts Stainless steel conforming to designation 04Crl8Ni10 or 07Crl8Ni9 of IS: 6603-1972* or IS: 6911-1972†, as applicable.
- 2.2 Rubber Parts Good quality natural rubber shall be used. It shall be capable of ageing in an air-oven for 168 hours at $70 \pm 1^{\circ}$ C without showing appreciable stiffening, softening, cracking or any other change in condition. The minimum tensile strength shall be $10^{\circ}29 \text{ MN/m}^2$ (105 kgf/cm^2) and $9^{\circ}31 \text{ MN/m}^2$ (95 kgf/cm^2) before and after ageing and minimum elongation at break shall be 400 and 300 percent, respectively.

2.3 Glass

- 2.3.1 Shall be clear, transparent glass of type I conforming to IS: 2303-1963‡, showing no evidence of corrosion, scumming, chipping or cracking when boiled in a closed vessel containing distilled water for six hours continuously.
- 2.4 Plastics Suitable for the purpose intended and shall not crack, flake, peel or otherwise react with the solutions used and shall not disintegrate in normal use.

3. SHAPE AND DIMENSIONS

- 3.1 Macintosh's pattern, spray shall conform to shapes and dimensions as given in Fig. 1.
- 3.2 Tolerances on various dimensions shall be permitted as given below:
 - a) ± 0.1 mm on dimensions up to 5.0 mm,
 - b) ± 0.2 mm on dimensions above 5.0 mm and up to 10.0 mm,
 - c) ± 0.5 mm on dimensions above 10.0 mm and up to 20.0 mm,
 - d) ± 1.0 mm on dimensions above 20.0 mm and up to 50.0 mm,
 - e) ±1.5 mm on dimensions above 50.0 mm and up to 100.0 mm, and
 - f) ± 2.0 mm on dimensions above 100.0 mm.

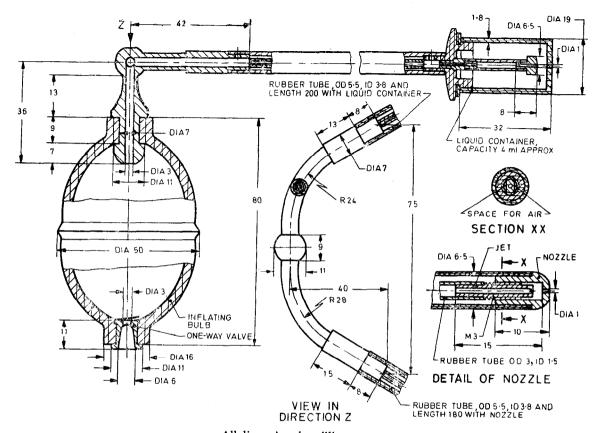
4. WORKMANSHIP AND FINISH

4.1 One end of the inflating bulb shall be securely fitted with an air inlet non-return valve. The other end shall be fitted with metallic tube as shown in Fig. 1.

^{*}Specification for stainless steel bars and flats.

[†]Specification for stainless steel plate, sheet and strip.

[!]Method of grading glass for alkalinity.



All dimensions in millimetres.
Fig. 1 Spray, Macintosh's Pattern

- 4.2 A small rubber tube of 3 mm outside diameter shall connect the liquid container with the nozzle. The screw threads in the liquid container shall conform to IS: 4218*. When the lid of the container is closed, it shall make an air and water tight.
- 4.3 The nozzle shall be firmly secured.
- 4.4 The metallic components shall be polished bright.

5. MARKING

- 5.1 Each component shall be marked with the manufacturer's name, initials or registered trade-mark.
- 5.1.1 Each component may also be marked with the ISI Certification Mark.

Note — The use of the ISI Certification Mark is governed by the provisions of the Indian Standards Institution (Certification Marks) Act and the Rules and Regulations made thereunder. The ISI Mark on products covered by an Indian Standard conveys the assurance that they have been produced to comply with the requirements of that standard under a well-defined system of inspection, testing and quality control which is devised and supervised by ISI and operated by the producer. ISI marked products are also continuously checked by ISI for conformity to that standard as a further safeguard. Details of conditions under which a licence for the use of the ISI Certification Mark may be granted to manufacturers or processors, may be obtained from the Indian Standards Institution.

6. TESTS

6.1 Performance Test

- **6.1.1** The liquid container shall be filled with water at room temperature to half of its height and the inflating bulb pressed 20 times. The quantity of water in 20 operations shall vary from 1.5 to 3.0 g, when the spray is kept horizontal.
- **6.1.2** When tested as specified in **6.1.1** in a place free from draught of air, the spray shall be visible against a glass plate placed at a distance of 70 cm approximately from the spray tip of the nozzle.
- **6.1.3** When tested as specified in **6.1.1**, a wet patch 4 cm in diameter shall be produced on a filter paper placed at a distance of 10 cm approximately.
- **6.1.4** The inflating bulb shall be pressed fully and quickly 100 times. On completion of the test, the rubber shall show no sign of damage.

^{*}Specification for ISO metric screw threads.

6.2 Autoclaving Test — After cooling the instruments to room temperature following the boiling test, place them unwrapped in a tray of the autoclave, then subject them to six separate cycles of $3\pm1/2$ minutes at a minimum temperature and pressure of $134^{\circ}\mathrm{C}$ and $200~\mathrm{kN/m^2}$ ($2.04~\mathrm{kgf/cm^2}$). After each cycle, open the autoclave, remove the instrument and tray and allow them to cool to room temperature.

Note — This test procedure prescribes a non-vacuum autoclaving method most commonly used in general surgical and dental practices. The test is not necessarily a valid criterion for performance under the most severe conditions produced in a vacuum autoclave.

7. PACKING

7.1 As agreed to between the purchaser and the supplier.

8. SCALE OF SAMPLING AND CRITERIA FOR CONFORMITY

- 8.1 Sampling and acceptance criteria for Macintosh's pattern sprays shall be as agreed to between the purchaser and the supplier. A recommended scheme for the same is given below.
- 8.2 Lot In any consignment, all the sprays produced from the same material, under similar conditions shall constitute a lot.
- 8.3 Number of sprays to be selected from each lot shall depend upon the size of the lot and shall be in accordance with col 1 and 2 of Table 1.

| TABLE 1 | SCALE OF SAMPLING |
|---------------|-------------------|
| LOT SIZE | Sample Size |
| Up to 15 | 2 |
| 16 " 50 | 3 |
| 51 " 150 | 5 |
| 151 and above | 8 |
| | |

8.3.1 These sprays shall be selected from the lot at random and in order to ensure the randomness of selection, procedures given in IS: 4905-1968* may be followed.

^{*}Method for randam sampling.

8.4 Number of tests and criteria for conformity of the sprays selected at random in accordance with col 1 and 2 of Table 1 shall be tested for shape and dimensions, workmanship and finish, performance test and corrosion resistance test. The lot shall be considered as conforming to these requirements if none of the sprays in the sample is found to be defective in any of these tests.



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